

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN 080993 AND 082093—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
Snyder Oil Corporation, Barrett Resources Corporation, Barrett Resources Corporation	93-1497	08/17/93
Paul Marciano, Guess?, Inc., Guess?, Inc.	93-1512	08/18/93
Armand Marciano, Guess?, Inc., Guess?, Inc.	93-1513	08/18/93
Cargill, Incorporated, Philip Morris Companies, Inc., Kraft Food Ingredients Corp	93-1232	08/19/93
The New York Times Company, Affiliated Publications, Inc., Affiliated Publications, Inc.	93-1411	08/19/93
Jordan Trust, The New York Times Company, The New York Times Company	93-1415	08/19/93
FMR Corp., Newco, Newco	93-1503	08/19/93
Questar Corporation, Newco, Newco	93-1516	08/19/93
Motorola, Inc., Theodore D. & Doreen Galszler, Indala Corporation	93-1468	08/20/93
Kaleo Investment Associates IV, L.P., Imo Industries Inc., Newco	93-1515	08/20/93
Dover Corporation, TCW Special Placements Fund III, BTG Holdings, Inc.	93-1517	08/20/93
AIF II, L.P., Zale Corporation, Zale Corporation	93-1526	08/20/93
Vestjyske Slagterier A.m.b.A., The East Asiatic Company Ltd. A/S, Plumrose USA, Inc.	93-1527	08/20/93
Beneficial Corporation, Textron Inc., Avco Financial Services, Inc.	93-1531	08/20/93
Richard E. Marriott & Nancy P. Marriott, Marriott Corporation, Marriott International, Inc.	93-1535	08/20/93
J.W. Marriott, Jr. & Donna Rose Marriott, Marriott Corporation, Marriott International, Inc.	93-1536	08/20/93
Alice S. Marriott, Marriott Corporation, Marriott International, Inc.	93-1537	08/20/93
Victor Foss, Victor Foss, Forcenergy Partners, L.P.	93-1546	08/20/93
The News Corporation Limited, The New York Post Co., Inc., The New York Post Co., Inc.	93-1556	08/20/93
Quantum Realty Trust, Travelers Corporation, The Travelers Insurance Company and The Travelers	93-1559	08/20/93
Nasell Co., Goody Products, Inc., Goody Products, Inc.	93-1560	08/20/93
Corisc Group Fund, L.P., AB Electrolux, Anaheim Manufacturing Co	93-1568	08/20/93
Dickstein & Co., L.P., P.A. Bergner & Co. Holding Company, P.A. Bergner & Co.	93-1570	08/20/93

FOR FURTHER INFORMATION CONTACT:

Sandra M. Peay or Renee A. Horton,
Contact Representatives, Federal Trade
Commission, Premerger Notification
Office, Bureau of Competition, Room
303, Washington, DC 20580, (202) 326-
3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 93-21137 Filed 8-30-93; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. 93E-0213]

Determination of Regulatory Review
Period for Purposes of Patent
Extension; Claritin®

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Claritin® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product. **ADDRESSES:** Written comments and petitions should be directed to the

Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John Ensign, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the

Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Claritin®. Claritin® (loratadine) is indicated for the relief of nasal and non-nasal symptoms of seasonal allergic rhinitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Claritin® (U.S. Patent No. 4,282,233) from Schering Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated July 15, 1993, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Claritin® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Claritin® is 3,751 days. Of this time, 1,395 days occurred during the testing phase of the regulatory review period, while 2,356 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* January 6, 1983. FDA has verified the applicant's claim that January 6, 1983, was the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* October 31, 1986. FDA has verified the applicant's claim that October 31, 1986 was the date the new drug application (NDA) for Claritin® (NDA 19-658) was initially submitted.

3. *The date the application was approved:* April 12, 1993. FDA has verified the applicant's claim that new drug application (NDA 19-658) was approved on April 12, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 731 days of patent extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before November 1, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 28, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.
[FR Doc. 93-21024 Filed 8-30-93; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 91F-0390]

Ciba-Geigy Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 1B4290) proposing that the food additive regulations be amended to provide for the safe use of C₇-C₉-branched alkyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate as an antioxidant in lubricants that have incidental food contact.

FOR FURTHER INFORMATION CONTACT: Mitchell Chessman, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9511.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 6, 1991 (56 FR 58656), FDA announced that a food additive petition (FAP 1B4290) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188. The petition proposed that § 178.3570 *Lubricants with incidental food contact* (21 CFR 178.3570) be amended to provide for the safe use of C₇-C₉-branched alkyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate as an antioxidant for use in lubricants that have incidental contact with food. Ciba-Geigy Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: August 13, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93-21025 Filed 8-30-93; 8:45 am]

BILLING CODE 4160-01-F

Social Security Administration

Privacy Act of 1974; Report of New Routine Use

AGENCY: Social Security Administration (SSA), Department of Health and Human Services (HHS).

ACTION: New routine use.

SUMMARY: In accordance with the Privacy Act (5 U.S.C. 552a(e)(11)), we are issuing public notice of our intent to establish a new routine use of information maintained in the system of records entitled "Earnings Recording and Self-Employment Income System,

HHS/SSA/OSR, 09-60-0059" (Earnings Record).

The proposed routine use will permit SSA to disclose tax return information to the Department of Veterans Affairs (VA), through September 30, 1997, to administer certain VA programs pursuant to section 6103(l)(7) of the Internal Revenue Code (IRC) (26 U.S.C. section 6103(l)(7)), as amended by section 602 of the Veterans' Benefits Act of 1992, Public Law (Pub. L.) No. 102-568.

We invite public comments on this publication.

DATES: The proposed routine use will become effective as proposed without further notice on October 1, 1993, unless we receive comments on or before that date which would warrant our preventing the routine use from taking effect. No information will be disclosed under the proposed routine use after September 30, 1997, unless otherwise specifically permitted by statute.

ADDRESSES: Interested individuals may comment on this proposal by writing to the SSA Privacy Officer, 3-D-1 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235. All comments received will be available for public inspection at the above address.

FOR FURTHER INFORMATION CONTACT: Ms. Joan Green, Social Insurance Specialist, Confidentiality and Disclosure Branch, Office of Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone 410-965-1739.

SUPPLEMENTARY INFORMATION:

I. Discussion of the Proposed Routine Use

On September 18, 1991, we published a routine use in the Federal Register (FR) (see 56 FR 47220) which provided that we would disclose information obtained from tax returns or schedules filed with the Internal Revenue Service (IRS) to the VA to administer various programs under title 38 of the United States Code. (The programs are identified below in the proposed routine use statement.) The basis for the routine use was section 6103(l)(7) of the IRC, as amended by section 8051 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, requiring the Commissioner of Social Security to disclose the information to the VA. Our authority under section 6103(l)(7) to disclose the information expired on September 30, 1992. We withdrew the routine use from publication in the Federal Register on November 24, 1992 (see 57 FR 55265).